



Grantees interested in participating in training workshops and follow-up onsite help may contact Audrey Smolkin (asmolkin@hrsa.gov) for referrals and further information.

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HIPAA PRIVACY CONSIDERATIONS

A diverse group of CAP grantees participated in a conference call on, to revisit the provisions of the HIPAA Regulation concerning privacy of health information. The Bush Administration has reopened the Regulation for comments until March 30, 2001. Policy changes are still possible throughout the comment period. The new date of publication is set for April 16, 2001, making the date of compliance April 16, 2003. The health care industry as a whole is (and cannot afford not to be) avidly interested in the Regulation's far-reaching requirements and its final form.

Since the Regulation's privacy provisions are extensive and complex, health care providers are seeking to develop systems that can handle its many permutations and to get a realistic picture of its probable effects on their day-to-day operations. To help clarify some of these issues, lawyers Robert Fulk, Michael Gloam, and Amy Wahl offered a useful analysis of pertinent information, as discussed within the following four questions:

Who is Covered by the Regulation?

There are three categories of covered entities:

- ◆ Health plans
- ◆ Health care clearinghouses
- ◆ Health care providers who transmit health information electronically

Health care providers who do not transmit health information electronically do not come under the Regulation. However, they become covered entities if they contract with vendors who provide electronic transmission for them. These "business associates" may be covered entities themselves. If they are not, the covered entity becomes responsible for vendor compliance the Regulation.

What are "Business Associates," as Defined by the Regulation?

Business associates are entities that perform functions involving individually identifiable health information on behalf of the covered entity or that have access to such information because of their association with the covered entity. They too must protect the privacy of the information. Though they may also be "covered entities," they are not necessarily so.

What Health Information Is Covered By The Regulation?

Protected health information (PHI) is any individually identifiable health information that is held or transmitted in any form – not only electronically, but also in writing and even verbally under some circumstances. The Regulation preempts state law regarding PHI only to the extent that the existing state law is less stringent. De-identified information does not come under the Regulation, but extreme care must be taken to be certain that such information cannot be re-identified.

What Constitutes “Permission” Under The Regulation?

Patients may give four types of permission, as described under the Regulation:

- ◆ Consent
- ◆ Authorization
- ◆ The opportunity to revoke all or part of their authorization
- ◆ The opportunity to agree or disagree with their health information

Consent is necessary for three things: treatment, payment, and health care operations, which cover a wide range of activities. Even when a database is already established, it is not wise to rely on previously obtained consents. Health care entities may have to segregate previously acquired information, and pre-existing consents may not be acceptable in all cases under the provisions of the Regulation. Exceptions to consent include emergency situations, cases where there is difficulty communicating but consent can be inferred, and cases when the law requires that an individual be treated.

The concept of authorization, which is required from an individual prior to disclosure of PHI, is outside the scope of consent. Treatment is not conditional upon providing authorization. Furthermore, there is a limit to an authorization (expiration), and an individual can revoke any part of her authorization at any time or even refuse to sign an authorization. Health care entities are responsible for developing ways to track such revocations and refusals. Significant penalties for unintentional and intentional disclosure are included in the Regulation.

An individual must also have the opportunity to agree or disagree with her record, and the health care entity must make other institutions that share this information aware of the individual's amendment. A patient can ask for an accounting of PHI that has been released, to whom and why – this is an essentially new requirement since the Regulation was published in December – and systems must be designed to meet this requirement. An individual may also restrict disclosure of PHI in some cases. Therefore, grantees must develop a process for managing these PHI requests.

Standards under the Regulation provide increased protection for individually identifiable health information. They also create new patient rights that make it necessary to develop systems with appropriate safeguards. For example, despite joint involvement in the care of an individual, multiple providers may not be able to share PHI without authorization. Therefore, providers may find it useful to work together to design a shared authorization form wherever possible. Common systems will diffuse the cost of meeting these requirements and functions may be shared. However, new risks to patient privacy can arise and care must be taken to ensure that PHI privacy is

maintained. Extensive training will be required at all levels of provider support and must include discussion of appropriate parameters for PHI implementation.

These new standards will clearly change the concept of privacy as it applies to protected health information and the systems that manage it. For continuing HIPAA developments, please visit <http://aspe.hhs.gov/admsimp/Index.htm>.

HIPAA PRIVACY CONSIDERATIONS CALL PARTICIPANTS:

Name	Organization
Allen Meyer	San Francisco Community Clinic Consortium
Ana O'Connor	Alameda County Medical Center
Andrea Radford	NC Office of Rural Health
Anne Witmer	Louisiana Public Health Institute
Anne Kircher	El Rio Santa Cruz, AZ
Audrey Smolkin	HRSA Philadelphia, PA
Barbara Eyeman	Powell Goldstein
Beryl Cochran	HRSA
Blair Whitney	Community Health Initiative
Bob Reasoner	Houston, TX
Brenda Theus	Memphis CAP
Carolyn Emanuel	Family Health Center, SC
Cheryl Dammons	HRSA
Christie Bordeaux	HRSA
Christine Thurston	Oregon CAP
Dave Fant	Shenandoah Valley Medical System, WV
Debbie L. Nuss	Community Health Council
Diane M. Erlandson	HRSA Boston
Dinah Surh (Fred Hull)	Sunset Park Family Health Center
Dwayne Edwards	Valley Health Systems, Inc., WV
Edgar Brisbon	PA CAP
Eunice Dorst	Community Health Council
Gail Urban	Community Health Council
Jackie Liefer	
James Aiken	LSU Health Sciences Center
Jason Ladmer	Community Health Council, KS
Jay McGath	HRSA
Jim Dickson	Copper Queen Community Hospital
Jo Paulla Baca	First Choice Community Healthcare
Joanna Omi	NYC CAP
JoAnne Jorgenson	Inova Health Care Services
John Cragin	Boston Medical
John Heard	Kirksville College of Osteopathic Medicine, MO
John Soria	Las Clinicas del Norte, NM
John Frana	Community Health Initiative
John Ussery	Las Clinicas del Norte, NM
Joyce Hospidarn	AZ Rural Health Office
Judith Chaconas	Delaware Health Care Commission

Judy Szalapski	MN CAP
Katherine Schneider	Middlesex Hospital
Kerrie Jones Clark	Rhode Island Health Center Association
Kevin Ryan	
Kim Beggs	Community Health Initiative
Laura Coleman	Bi-State Primary Care Coordination
Linda Potts	Community Health Initiative
Lisa Craig	Health Improvement Partnership, Spokane WA
Liz Whitley	Denver Health
Luanne Nyberg	Hennepin County Med Center, MN
Lucinda Stinson	KCMS/Healthy Futures, MI
Lynn Evans-Reister	Inova Health Care Services
MAC	
Mark Snyder	Cherokee Health Systems, TN
Mary Colleen Bryan	Colorado Dept of Health Policy & Financing
Matt All	Kansas Insurance Department
Michael Head	Cincinnati Health Network Inc.
Michelle Sawyer	Taking Place of Tom Irons
Mike De Lucca	Broward County FL
Nick Zucconi	HRSA Denver
Nina Sporn	NY City Health & Hospital
Pat McCarver	Yavapai County Health Department in Arizona
Leslie Lightfoot	Yavapai County Health Department in Arizona
Paula Roy	Delaware Health Care Commission
Paula Lucey	Milwaukee CAP
Joseph Cooper	Milwaukee CAP
Ray Greedy	CHOICE Regional Health Network
Remetta Lloyd	NY City Health & Hospital
Ricky Pitterman	Middlesex CAP
Robert Falk	
Robin Lawrence	Delaware Health Care Commission
Rommel Nobay	Middlesex CAP
Seema Verma	Marion County CAP Health & Hospital Corporation of Marion County
Stacy Kelly	Daughters of Charity Health Services, TX
Stephen Dorage	HRSA Atlanta
Susan Glick	Connecticut Office of Healthcare Access
Tammy Eberly	Tiahoga CAP
Tammy Stoltz	PCAP Pima Community Access Program
Tess Stack Kuenning	Bi-State Primary Care Coordination, NH
Thomas Kring	HRSA
Tom Brown	Palmetto Alliance, Columbia SC
Tom Butts	Jefferson County Department of Health, Birmingham Alabama
Tom Lewis	MD CAP
Tracey Bush	Louisiana Public Health Institute
Synthesis Writers	Synthesis Professional Services